commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 50707, Sept. 27, 1996]

§ 872.3520 OTC denture cleanser.

(a) *Identification.* An OTC denture cleanser is a device that consists of material in the form of a powder, tablet, or paste that is intended to remove debris from removable prosthetic dental appliances, such as bridges or dentures. The dental appliance is removed from the patient's mouth when the appliance is cleaned.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38798, July 25, 2001]

§ 872.3530 Mechanical denture cleaner.

(a) *Identification.* A mechanical denture cleaner is a device, usually AC-powered, that consists of a container for mechanically agitating a denture cleansing solution. The device is intended to clean a denture by submersion in the agitating cleansing solution in the container.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[55 FR 48439, Nov. 20, 1990, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38798, July 25, 2001]

§ 872.3540 OTC denture cushion or pad.

(a) *Identification.* An OTC denture cushion or pad is a prefabricated or noncustom made disposable device that is intended to improve the fit of a loose or uncomfortable denture, and may be available for purchase over-the-counter.

(b) *Classification.* (1) Class I if the device is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth. The device is intended to be discarded following 1 day's use. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9.

(2) Class II if the OTC denture cushion or pad is made of a material other than wax-impregnated cotton cloth or if the intended use of the device differs from that described in paragraph (b)(1) of this section. The special controls for this device are FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical—Devices Part I: Evaluation and Testing,' '' and

(ii) ''OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.''

[52 FR 30097, Aug. 12, 1987, as amended at 65 FR 2315, 2000; 65 FR 17144, Mar. 31, 2000]

§ 872.3560 OTC denture reliner.

(a) *Identification.* An OTC denture reliner is a device consisting of a material such as plastic resin that is intended to be applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. The device is intended to replace a worn denture lining and may be available for purchase over the counter.

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' '' and

(2) ''OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.''

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 50707, Sept. 27, 1996; 65 FR 17144, Mar. 31, 2000]

§ 872.3570 OTC denture repair kit.

(a) *Identification.* An OTC denture repair kit is a device consisting of a material, such as a resin monomer system of powder and liquid glues, that is intended to be applied permanently to a denture to mend cracks or breaks. The device may be available for purchase over-the counter.

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' '' and

(2) ''OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.''

[52 FR 30097, Aug. 12, 1987, as amended at 65 FR 17144, Mar. 31, 2000]

§ 872.3580 Preformed gold denture tooth.

(a) *Identification.* A preformed gold denture tooth is a device composed of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use as a tooth or a portion of a tooth in a fixed or removable partial denture.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38798, July 25, 2001]

§ 872.3590 Preformed plastic denture tooth.

(a) *Identification.* A preformed plastic denture tooth is a prefabricated device, composed of materials such as methyl methacrylate, that is intended for use as a tooth in a denture.

(b) *Classification.* Class II.

§ 872.3600 Partially fabricated denture kit.

(a) *Identification.* A partially fabricated denture kit is a device composed of connected preformed teeth that is intended for use in construction of a denture. A denture base is constructed using the patient's mouth as a mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are chemically bonded to the base.

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' '' and

(2) ''OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.''

[52 FR 30097, Aug. 12, 1987, as amended at 65 FR 17144, Mar. 31, 2000]

§ 872.3640 Endosseous implant.

(a) *Identification.* An endosseous implant is a device made of a material such as titanium intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 872.3.

§ 872.3645 Subperiosteal implant material.

(a) *Identification.* Subperiosteal implant material is a device composed of titanium or cobalt chrome molybdenum intended to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device is intended to provide support for prostheses, such as dentures.

(b) *Classification.* Class II.